Massachusetts Department of Public Health (MDPH)
Immunization Program

Model Standing Orders

Quadrivalent Human Papillomavirus (HPV), Types 6/11/16/18, Vaccine

These model standing orders are current as of March 2007. They should be reviewed carefully against the most current recommendations and may be revised by the clinician signing them.

Approved Formulation of HPV Vaccine*

Vaccine Manufacturer	Vaccine Trade Name	HPV Types	Approved Age Group
Merck & Co. Inc	Gardasil®	6/11/16/18	girls & women 9-26 years of age

***** Currently, HPV vaccine is **not** approved for use in girls less than 9 years of age, women older than 26 years of age, or males of any age.

HPV is indicated for the prevention of cervical cancer, precancerous or dysplasic lesions of the cervix, vagina, and vulva, and genital warts in girls and women ages 9 to 26 years of age caused by HPV types 6,11,16 and 18 for the following groups:

- Routine vaccination with three doses of quadrivalent HPV vaccine is recommended for females 11-12 years of age.
  - The vaccination series can be started as young as 9 years of age
- Catch-up vaccination is recommended for females 13-26 years of age who have not been vaccinated previously or who have not completed the full vaccine series.
  Note: At present time, no booster dose is recommended upon completion of a 3-dose series.

Order:

1. Provide patient, parent or legal representative with a copy of the Vaccine Information Statement (VIS) and answer any questions. The vaccine information statement (VIS) for quadrivalent HPV can be found at www.immune.org/vis.

2. Screen for contraindications according to Table 1 on page 2.

3. **Shake well before use.** Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. After thorough agitation, Gardasil® is a white, cloudy liquid.
Note: See the package insert for specific instructions for using single dose prefilled syringes.

4. Administer 0.5mL of quadrivalent HPV vaccine intramuscularly (IM) in the deltoid muscle according to the schedule. (See Table 2) **Always check package insert prior to administration of any vaccine.**

The correct needle size is important to ensure injection into the deeper muscle mass and decrease local reactions. See table below:

Sex/weight	Needle Length
Female <60 kg (130 lbs)	1” (25 mm)
Female 60-90 kg (130-200 lbs)	1”- 1 ½” (25-38 mm)
Female >90 kg (200 lbs)	1 ½” (38 mm)

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Clinician’s Signature Date

5. Administer HPV vaccine simultaneously with all age appropriate vaccines that are recommended, such as Tdap, Td and MCV4, but at a different site.

6. If possible, observe patient for an allergic reaction for 15 minutes after administering vaccine. **Note:** Syncope (vasovagal or vasodepressor reaction) can occur after vaccination, most commonly among adolescents and young adults. Of these observed syncopal episodes, 89% occur within 15 minutes after vaccination.

7. Have facilities and personnel available for treating immediate hypersensitivity reactions.

8. Report clinically significant adverse reactions to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967, or via the VAERS website: http://vaers.hhs.gov.

9. See the MDPH, Immunization Program document, *General Protocols for Standing Orders*, for recommendations and requirements regarding vaccine administration, documentation, and consent.

Table 1. Contraindications, Precautions and Special Situations, and Guidance for Administration of Quadrivalent HPV Vaccine

<table>
<tr><th>Valid Contraindications to Quadrivalent HPV Vaccine</th><th>Invalid Contraindications/Precautions to Quadrivalent HPV Vaccine (HPV vaccine should be administered)</th></tr>
<tr><td rowspan="2">Severe allergic reaction (e.g. anaphylaxis) to a previous dose of quadrivalent HPV vaccine, yeast, or any other component of the vaccine.
(Gardasil® does not contain a preservative or antibiotics)</td><td>Minor acute illness, with or without fever</td></tr>
<tr><td>Special Situations and Guidance for Administration of Quadrivalent HPV Vaccine</td></tr>
<tr><td>Valid Precautions to Quadrivalent HPV Vaccine</td><td>Equivocal or abnormal Pap test [2]</td></tr>
<tr><td rowspan="2">Vaccination of people with moderate to severe illness should be deferred until after illness improves. (temporary precaution)</td><td>Breastfeeding [3]</td></tr>
<tr><td>Immunosuppression [4]</td></tr>
<tr><td>Pregnancy [1]</td><td>Anticoagulation or bleeding disorder [5]</td></tr>
</table>

[1] **Pregnancy:** HPV vaccine is not recommended for use in pregnancy. The vaccine has not been associated causally with adverse outcomes of pregnancy or adverse events to the developing fetus. However, data on vaccination during pregnancy are limited. Any exposure to vaccine during pregnancy should be reported to Merck's HPV vaccine pregnancy registry (1-800-986-8999).

If a dose of vaccine has been administered during pregnancy, no intervention is needed. If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose regimen should be delayed until after completion of the pregnancy.

[2] Quadrivalent HPV vaccine can be given to females who have an equivocal or abnormal Pap test, a positive Hybrid Capture II® high risk test, or genital warts. Vaccine recipients should be advised that there are not data to indicate that the vaccine has any therapeutic effect on existing Pap test abnormalities, HPV infection or genital warts. Vaccination of these females would provide protection against infection with vaccine HPV types not already acquired.

[3] Breastfeeding women can receive quadrivalent HPV vaccine.

[4] Females who are immunocompromised either from disease or medication can receive quadrivalent HPV vaccine. However the immune response to vaccination and vaccine effectiveness might be less than in females who are immunocompetent.

[5] Minimize the risk of bleeding after an IM injection by administering the vaccine immediately after the patient has received antihemophilia or other appropriate coagulation replacement therapy. Use a 23-gauge (or smaller) needle with immediate application of direct pressure to the vaccination site for $\geq$ 2 minutes.

Table 2. HPV Vaccine Schedule

Dose	Schedule	Minimum Age/Interval[1,2,3]
1st Dose	0 mos	9 years
2nd Dose	2 mos (2 mos after 1st)	4 weeks (after 1st)
3rd Dose[4]	6 mos (6 mos after 1st)	12 weeks (after 2nd)

[1] There are no maximum intervals.
[2] If the schedule is interrupted, the vaccine series does not need to be repeated.
[3] The vaccine is licensed for females with a minimum age of 9 years and a maximum age of 26 years.
[4] No booster dose is currently recommended.

Notes on HPV and Cervical Cancer Screening:
Cervical cancer screening recommendations have not changed for females who receive HPV vaccine.

- 30% of cervical cancers are caused by HPV types not prevented by immunity provided by quadrivalent HPV vaccine
- Vaccinated females could subsequently be infected with non-vaccine HPV types
- Sexually active females could have been infected prior to vaccination
- Providers should educate women about the importance of cervical cancer screening and measures to reduce the risk of acquiring HPV infection.

References:
CDC. Quadrivalent Human Papillomavirus Vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2007;56: 1-24. Available at:
http://www.cdc.gov/mmwr/PDF/rr/rr56e312.pdf

Gardasil® Package Insert. Available at:
http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf

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Clinician's Signature Date

CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2006;55(RR15):1-48. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm?s_cid=rr5515a1_e

National Vaccine Advisory Committee. Standards for child and adolescent immunization practices. Pediatrics 2003;112:958-963.

A Human Papillomavirus Vaccine. The Medical Letter August 14/28, 2006; 48:65-66.

Human Papillomavirus: HPV Information for Clinicians—CDC Brochure. Available from: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA. Available at http://www.cdc.gov/std/hpv/hpv-clinicians-brochure.htm. [Accessed November 20, 2006.]

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